

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA
ex rel. PETER HUESEMAN,
Plaintiff,

v.

PROFESSIONAL COMPOUNDING
CENTERS OF AMERICA, INC.,
Defendant.

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CASE #: 5:14-cv-00212-XR

**DEFENDANT’S REPLY BRIEF IN SUPPORT OF MOTION FOR SUMMARY
JUDGMENT ON LACK OF PROOF OF CAUSATION AND DAMAGES**

The gravamen of Defendant PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, INC. [PCCA]’s Motion is that the Government has no evidence to carry its burden to prove that something PCCA did or failed to do either (a) caused any identifiable pharmacy to present any false or fraudulent claim to TRICARE/ESI or (b) the Government or its PBM Express Scripts to pay same. In the Motion PCCA fulfilled its “initial burden” under *Celotex*. This places the burden of proof squarely on the Government (and/or Relator Hueseman) to come forward with competent *evidence* to sustain these twin burdens. Significantly, the evidence must be in a form that is “admissible” at trial. Rule 56(c)(2).

Argument and Authorities

I. THE EVIDENCE – OR LACK THEREOF.

The Government’s Response cites no admissible evidence to establish either form of causation. To be sure, it cites evidence that shows things that did not even need to be shown by evidence because PCCA readily admitted them in its pleadings, including (i) that on or about March 7, 2012, PCCA President Jim Smith made the difficult decision to increase PCCA’s “AWPs” for its ingredients to levels that were commensurate with those published by its competitors, and (ii) that its sales personnel sometimes called that to the attention of customers

who appeared to focus their buying decisions on the AWP. But what is missing is evidence to connect the dots from these facts to even one “presentment” or “payment” of a claim, much less to the hundreds of thousands of claims for which the Government now seeks to recover over \$350 million in damages. In other words, there is a lot of smoke, but no fire whatsoever. The arguments of Government counsel, although very well worded and understandably “adversarial” are just that, i.e., arguments, not competent summary judgment proof. Succinctly stated, the Government has failed to carry its summary judgment burden and the Court must grant PCCA’s Motion.

As PCCA pointed out in its motion, the Government’s Rule 26 Disclosures identify only two actual pharmacists as potential witnesses in this case, i.e., Relator Hueseman, whose now-released Bellevue pharmacy cheated the Government in various ways, but mainly by “manipulating” its U&C (which has nothing to do with PCCA), and Richie Ray, who was not paid anything based on “AWP” but who told both TRICARE and ESI on October 21, 2013, that they were paying him 5x his PCCA “acquisition costs” but that, if they were paying full, undiscounted AWP to other pharmacies, as reported, it was 65x. The Government’s Response contains no affidavit, declaration, or other admissible testimony from any other pharmacist, or any other person with the requisite Rule 602 “personal knowledge” to establish that anything about PCCA’s published AWP or its marketing efforts actually “caused to be presented” any identifiable claim. As stated before, absent this evidence, summary judgment for PCCA is required by Rule 56.

Nor is there any competent summary judgment proof to establish that PCCA “caused” even a single dollar of damages to the Government. IF PCCA bore the burden of proof, we could now and would now provide the Court with additional competent summary judgment proof showing both (A) that *the* person in charge of the \$7B/year TRICARE contract for ESI recently testified that “[t]he industry running joke is that AWP stands for ain’t what’s paid,” and (B) that the extremely troubling ESI claims data, upon which the Government’s claim for damages rests,

reflects that for the entire damages period the total amount actually paid “based on AWP” was only \$921,063.¹ But PCCA does not bear the burden of proof and this evidence is neither before the Court in support of this particular Motion nor necessary for the granting of this Motion. It is mentioned only because it will undoubtedly be discussed at the forthcoming status hearing and oral argument on January 2, 2024, in the context of other pending motions.

Finally, it is also significant that in spite of the fact that the filing of this Response was delayed by four weeks, to be at a due date *after* the deadline for the Government to disclose experts, there is no declaration or affidavit from any of the Government’s expert witnesses. This is extremely curious because both in its arguments to this Court against permitting PCCA to take a 30(b)(6) deposition, and in the deposition of Captain Norton himself, it was suggested that the real proof of damages would come via expert testimony. PCCA believes that, in all probability, the Government’s decision not to attach an affidavit or declaration from an expert stems from the fact that, upon reading the expert reports, we immediately notified Government counsel of our very significant *Daubert* concerns about the “reliability” and admissibility of those expert opinions. For present purposes, however, it does not matter “why” the Government chose not to submit an affidavit or declaration from its experts. The Government has the burden of proof and, pursuant to Rule 56(c)(2) PCCA vehemently objects to the factual contention that its actions or inactions “caused” either presentment or payment on the ground that there is no competent “admissible” evidence to establish that contention. Argument does not suffice; evidence is required.

¹ Yet, even that number is inflated. Recently obtained evidence from ESI shows that it did not even start paying for all ingredients included within a compound as required by D.0 until its TRICARE business was “migrated” to ESI’s new “Foundation 14” platform in July 2013.

As the Court will later learn, the ESI computers did document that over \$500 million was paid out “based” on something coded as ACQ. Neither the Government nor ESI has yet seemed to be able to advise as to what ACQ *is*. However, it is abundantly clear what it is **not**. It is not AWP!

The test for adequacy of summary judgment proof mirrors the standard for adequacy for submission of a fact question to a jury in the context of a JMOL at trial, i.e., that “no reasonable jury” could, with the evidence presented, “believe” that the alleged fact was true. *Scott v. Harris*, 550 U.S. 372, 380 (2007). This Court cited and quoted *Scott* for precisely this teaching in *Hampton v. Pamerleau*, No. SA-14-CA-806-XR, 2015 WL 4953084, at *8 (W.D. Tex. Aug. 18, 2015), as follows: “The Supreme Court explained in *Scott* that:

At the summary judgment stage, facts must be viewed in the light most favorable to the nonmoving party only if there is a ‘genuine’ dispute as to [the] facts. As we have emphasized, “[w]hen the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts ... Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no ‘genuine issue for trial.’ “ “The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact.” “When opposing parties tell two different stories, one of which is blatantly contradicted by the record, so that no reasonable jury could believe it, a court should not adopt that version of the facts for purposes of ruling on a motion for summary judgment.”

Id. at n.27. *Accord Richardson v. Univ. of Texas Sys.*, No. 5:19-CV-00271-XR, 2020 WL 1159038, at *4 (W.D. Tex. Mar. 9, 2020); *Neddo v. New Prime, Inc.*, No. 5:18-CV-00139-XR, 2019 WL 2549231, at *3 (W.D. Tex. June 20, 2019)(“no reasonably jury could find . . .”).²

The Government’s pleading tells a troubling “story” that, in the 12(b)(6) context, this Court had to accept as true. But at this stage of the litigation the Court must view the evidence, and the lack thereof, through an entirely different procedural prism. Because the Government has adduced no competent summary judgment proof to establish either form of causation, both of which are

² Indeed, this Court recently granted summary judgment on precisely this basis in another case. *Holt v. Wal-Mart Store, Inc.*, No. SA-20-CV-01476-XR, 2022 WL 272117, at *6 (W.D. Tex. Jan. 18, 2022)(“The Court will not assume in the absence of any proof that Plaintiff could substantiate this theory and must grant summary judgment where, as here, no reasonable jury could return a verdict for the nonmovant.”).

required under the law, and further because many of its claims are “blatantly contradicted by the record,” including its false claim in paragraph 45 of its Complaint in Intervention that it actually required submission of acquisition costs and paid or “would have paid” based on them, this Court should not “adopt that version of the facts for purposes of ruling on a motion for summary judgment.” *Id.*

II. CLARIFYING THE LAW.

The Government’s Response also makes three legal arguments which must be addressed.

A. Subsection (A) vs. (B). First it contends that 31 U.S.C. §§ 3729(a)(1)(A) and (B) have different causation requirements. In its Response, the Government attempts to address the “causes to be presented” language in § 3729(a)(1)(A) directly. By contrast, it attempts to circumvent the analysis altogether with respect to § 3729(a)(1)(B) by claiming that “PCCA’s causation arguments are irrelevant to these claims.” Doc. 160 at 26.

Section 3729(a)(1)(B) imposes liability on one who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” The Government claims that because PCCA reported its AWP’s to commercial pricing compendia, it is liable for directly making “a false record or statement,” without any showing that the reporting was “made” to the Government or that it caused submission of a false claim. Doc. 160 at 26. The Fifth Circuit, sitting *en banc*, disagrees. Noting that the FCA “was not intended to impose liability for every false statement made to the government,” the Court held that “[t]here is no liability under this Act for a false statement unless it is used to get [a] false claim paid.” *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 675 & n. 17 (5th Cir. 2003) (*en banc*) (internal citation omitted). This recognizes that causation is integral to liability under subsection B as well as subsection A. Moreover, it is significant that the *En Banc* Fifth Circuit noted that the focus under subsection B is on false statements “made to the government.” PCCA made no statements

whatsoever to the government and it presented no claims to the Government. It published AWP's in industry compendia. Because there is no competent evidence that PCCA caused any claim to be presented or paid, summary judgment is appropriate under both subsections.

B. “Injury in Fact” is Prerequisite for Assessment of Statutory Penalties. Second, the Government contends that, even without damages, PCCA could still be liable for statutory penalties. To be sure, PCCA certainly acknowledges that the Fifth Circuit panel opinion in *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009), reads that even if they do not cause monetary damages, “[a] person that **presented** fraudulent claims that were never paid remains liable for the Act’s civil penalty.” *Id.* at 189 (emphasis added). However, there are several reasons why this curious language in a 14-year-old panel opinion does not justify a denial of the summary judgment motion in this case. First, it is contrary to the language by the *En Banc* court in *Southland Management* that “[t]here is no liability under this Act for a false statement unless it is used to get [a] false claim paid.” *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 675 & n. 17 (5th Cir. 2003) (*en banc*).³ Judge Martinez of this District considered the Government’s reliance on *Grubbs* in *U.S. ex rel. Gonzalez v. Fresenius Med. Care N. Am.*, 748 F. Supp. 2d 95, 116 (W.D. Tex. 2010), *aff’d sub nom. Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470 (5th Cir. 2012), concluding that to the extent that there is a conflict between *Grubbs* and *Southland*

³ PCCA acknowledges that Congress amended the Act in 2009 to remove the phrase “to get a false or fraudulent claim paid or approved.” This was obviously done in response to Justice Alito’s opinion in *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662 (2008). However, the statutory phrase was replaced with a “materiality” requirement, which, of course, brings us to *Escobar. Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 196 (2016) (“We emphasize, however, that the False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations.”). There is still no clear indication of a congressional purpose to punish defendants with statutory penalties without proof that they presented claims to the Government and that the Government sustained damages or harm thereby.

Management on this point, “the Court is bound by the clear holding of *Southland Management*.” 748 F. Supp. 2d at 116 & n. 37. *Southland Management* was, of course, an *en banc* decision.

Second, under Supreme Court authority a holding that a person or company can be liable for statutory penalties without a showing of some actual harm or damage to the Government would be contrary to the basic “standing” requirements for a *qui tam* plaintiff. *Vermont Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 771 (2000) (To establish “standing” the plaintiff must “demonstrate ‘injury in fact’—a harm that is both ‘concrete’ and ‘actual or imminent, not conjectural or hypothetical.’”).

Third, the language of *Grubbs* itself seems to confine the liability for such penalties to persons who have actually “presented” the claim, i.e. not to someone like PCCA who is alleged to have caused someone else to submit such a claim.⁴ For these reasons, even if the Government had proof that PCCA “caused to be presented” any false claim – which it does not have – the assessment of statutory penalties without proof of actual damage to the Government would be contrary to law, to common sense, and, with respect, to Due Process.⁵

C. The Common Law Claims Do Not Save the Government. The Government’s final “anchor-to-windward” is an argument that, even if it has no proof of damages under the FCA/AKS, it can still proceed under common law claims for payment by mistake, unjust enrichment, and fraud under federal common law. Doc. 66 at 44-46. There are two fundamental

⁴ Additionally, although *Grubbs* has not been cited in support of the Government’s position in the 14 years since it was handed down, a Westlaw search shows that it has been negatively criticized in 35 subsequent opinions.

⁵ If there were proof that PCCA actually caused any identifiable claim to be presented, the Court could, by expanding the language in *Grubbs* and ignoring the contrary verbiage in the *en banc* opinion in *Southland Management* grant partial summary judgment on the damages claims but reserve the penalties remedy until post-verdict. However, because there is no proof of presentment, summary judgment on all claims is appropriate.

problems with this approach. First, both unjust enrichment and payment by mistake are designed to require a person or company to disgorge money that it has received from the plaintiff. There is a myriad of citations on point. *See e.g. Burlington N. R. Co. v. Sw. Elec. Power Co.*, 925 S.W.2d 92, 97 (Tex. App. 1996)(“When a defendant has been unjustly enriched by the receipt of benefits in a manner not governed by contract, the law implies a contractual obligation upon the defendant to restore the benefits to the plaintiff.”), writ granted (June 12, 1997), *aff’d sub nom. Sw. Elec. Power Co. v. Burlington N. R.R. Co.*, 966 S.W.2d 467 (Tex. 1998); *Lincoln Nat. Life Ins. Co. v. Rittman*, 790 S.W.2d 791, 792 (Tex. App. 1990)(payor is entitled in equity “to restitution from the other” who received the payment). PCCA has received no taxpayer dollars from either ESI or TRICARE.

With regard to the federal common law fraud claim, these are available only when there is no express contract governing the payments at issue. *Albrecht v. Committee on Emp. Benefits of Fed. Rsrv. Emp. Benefits Sys.*, 357 F.3d 62, 69 (D.C. Cir. 2004). In this case, there are contracts between TRICARE and ESI, between ESI and the pharmacies which submitted the claims and between PCCA and the pharmacies. See Doc. 66 at 10, ¶¶ 40-41. Because all parties’ relationships were governed by express contracts, the Government’s common law claims are not viable. In that regard, PCCA does acknowledge that the Court denied its motion to dismiss these theories. Doc. 109 at 37-43. But this issue was not presented in that context. Doc. 84 at 55-60.⁶

⁶ In its analysis of the motion to dismiss, the Court relied significantly on *United States ex rel. Campbell v. KIC Dev., LLC*, No. EP-18-CV-193-KC, 2019 WL 6884485 (W.D. Tex. Dec. 10, 2019). In *Campbell*, Judge Cardone cited *Albrecht* for the general principle set forth above, but noted an exception to the rule in a False Claims Act case in which the Government claims that it was fraudulently induced to enter the contract, rendering the contract void. *Id.* at *17. In this case, the Government does not claim that any of the contracts are void based on fraudulent inducement.

Interestingly, Judge Cardone also noted that the “void contract” exception “derives from two Supreme Court cases, which held that the United States may cancel contracts tainted by kickbacks

Once again there are numerous citations available regarding this elusive federal common law cause of action. Indeed, a Westlaw search on point in the 5th Circuit database yields 1044 cases. An exhaustive brief on point would be exhausting for counsel and the Court. All that need be said at this juncture is that the Fifth Circuit has been fairly dubious about such claims. *See e.g., Wright v. Allstate Ins. Co.*, 500 F.3d 390, 394-955 (5th Cir. 2007); *Easterling v. S. Farm Bureau Cas. Ins. Co.*, No. 2:20-CV-0025-KS-MTP, 2020 WL 6947903, at *3 (S.D. Miss. June 24, 2020)(“Here, Plaintiffs are merely attempting to re-labeled their state law fraud claims as ‘federal common law’ fraud claims. Nevertheless, under *Wright*, such claims are extra-contractual and not allowed.”).

Conclusion

The Government has not sustained its burden of proof and “no reasonable jury” could find PCCA liable under any theory of liability alleged based on the actual evidence before the Court. Therefore, summary judgment on all theories of liability is appropriate.

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or other fraud or wrongdoing. *See United States v. Mississippi Valley Generating Co.*, 364 U.S. 520, 565–66, (1961); *United States v. Acme Process Equip. Co.*, 385 U.S. 138, 146–48, (1966).” *Id.* at *17. The concept that the Government can only assert common law claims when accompanied by claims that the underlying contract is void is thus directly analogous to the concept that the Government can only recover all damages “tainted” by fraud when the Government proves that it was induced to enter into the contract at issue by fraud or kickbacks. Both must include a claim that the underlying contracts were void in order to be viable. *See* PCCA’s discussion of *United States ex rel. Longhi v. United States*, 575 F.3d 458, 473 (5th Cir. 2009), Doc. 144 at 30-32. As PCCA explained in its motion, *Longhi*’s reasoning has been quoted to support the “tainted” damages theory in a narrow category of Anti-Kickback Statute cases.

Respectfully submitted,

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Certificate of Service

I hereby certify that on December 15, 2023, Defendant's Reply Brief in Support of Motion for Summary Judgment on Lack of Proof of Causation and Damages was electronically filed with the Clerk of Court using the ECF system, that will send an email notification of such filing to the following counsel of record:

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